

Attorney Docket No. 9448-51



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Thomas W. Leonard  
Application No.: 10/821,278  
Filed: April 8, 2004  
For: METHODS OF ADMINISTERING ESTROGENS AND PROGESTINS

Confirmation No.: 1153  
Group Art Unit 1614

Date: November 23, 2004

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)**

Sir:

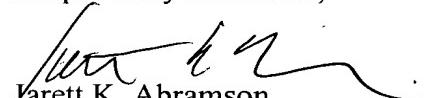
Attached is a list of documents on Form PTO-1449, together with a copy of any listed foreign patent document and/or non-patent literature. A copy of any listed U.S. patent and/or U.S. patent application publication is not provided herewith in accordance with the waiver by the U.S. Patent and Trademark Office of requirements under 37 C.F.R. § 1.98(a)(2)(i) for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC § 371 after June 30, 2003. Also enclosed is a translation or a concise explanation of each non-English language document enclosed.

It is requested that these documents be considered by the Examiner and officially made of record in accordance with the provisions of 37 C.F.R. § 1.56 and Section 609 of the MPEP.

No fee is believed due. However, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

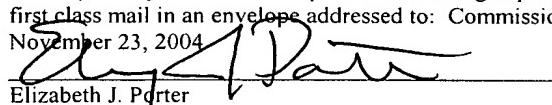
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P. O. Box 37428  
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Telephone: (919) 854-1400  
Facsimile: (919) 854-1401  
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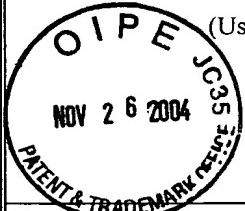
Respectfully submitted,

  
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Registration No. 47,376

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I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on November 23, 2004.

  
Elizabeth J. Porter

<b>FORM PTO-1449</b> U.S. Department of Commerce Patent and Trademark Office		Attorney Docket Number: 9448-51	Serial No. 10/821,278
LIST OF DOCUMENTS CITED BY APPLICANT			
(Use several sheets if necessary)			
			
Applicants: Thomas W. Leonard			
Filing Date: April 8, 2004			Group 1614

## U. S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	1.	3,230,142	1/18/66	Spero	167	55	
	2.	3,487,152	12/30/69	Carstensen et al.	424	240	
	3.	3,502,772	3/24/70	Ijzerman	424	239	
	4.	3,568,828	3/9/71	Lerner	206	42	
	5.	3,591,688	7/6/71	Jones et al.	424	239	
	6.	3,639,600	2/1/72	Hendrix	424	242	
	7.	3,733,407	5/15/73	Segre	424	239	
	8.	3,795,734	3/5/74	Rochefort	424	238	
	9.	3,836,651	9/17/74	Rudel et al.	424	239	
	10.	3,813,418	05/28/74	Hofmeister et al.	260	397.4	
	11.	3,932,635	1/13/76	Segre	424	239	
	12.	3,939,264	2/17/76	Lachnit-Fixson	424	239	
	13.	3,942,641	3/9/76	Segre	206	534	
	14.	3,957,982	5/18/76	Lachnit-Fixson et al.	424	238	
	15.	3,969,502	7/13/76	Lachnit-Fixson	424	239	
	16.	4,027,019	5/31/77	Shroff	424	238	
	17.	4,066,757	1/3/78	Pasquale	424	243	
	18.	4,071,623	1/31/78	van der Vies	424	238	
	19.	4,145,416	3/20/79	Lachnit-Fixson et al.	424	238	
	20.	4,147,783	4/3/79	van der Vies	424	243	
	21.	4,154,820	5/15/79	Simoons	424	175	
	22.	4,210,644	7/1/80	Ewing et al.	424	239	
	23.	4,259,325	3/31/81	Prezewowsky et al.	424	238	
	24.	4,291,028	9/22/81	Vorys	424	238	
	25.	4,292,315	9/29/81	Vorys	424	240	

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Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	26.	4,315,925	2/16/82	Hussain et al.	424	239	
	27.	4,327,725	5/4/82	Cortese et al.	128	260	
	28.	4,378,356	3/29/83	De Jager	424	238	
	29.	4,383,993	5/17/83	Hussain et al.	424	239	
	30.	4,390,531	6/28/83	Edgren	424	239	
	31.	4,425,339	1/10/84	Pitchford	424	239	
	32.	4,512,986	4/23/85	Reel et al.	514	170	
	33.	4,530,839	7/23/85	Pasquale	514	171	
	34.	4,544,554	10/1/85	Pasquale	514	170	
	35.	4,616,006	10/7/86	Pasquale	514	170	
	36.	4,621,079	11/4/86	Lachnit-Fixson et al.	514	170	
	37.	4,628,051	12/9/86	Pasquale	514	170	
	38.	4,738,957	4/19/88	Laurent et al.	514	182	
	39.	4,756,907	7/12/88	Beck et al.	424	85	
	40.	4,762,717	8/9/88	Crowley, Jr.	424	425	
	41.	4,764,378	8/16/88	Keith et al.	424	435	
	42.	4,783,337	11/8/88	Wong et al.	424	468	
	43.	4,816,257	3/28/89	Buster et al.	424	430	
	44.	4,816,258	3/28/89	Nedberge et al.	424	448	
	45.	4,826,831	5/2/89	Plunkett et al.	514	170	
	46.	4,855,305	8/8/89	Cohen	514	171	
	47.	4,900,734	2/13/90	Maxson et al.	514	171	
	48.	4,914,089	4/3/90	Tax	514	170	
	49.	4,921,843	5/1/90	Pasquale	514	170	
	50.	4,962,098	10/9/90	Boissonneault	514	170	
	51.	4,977,147	12/11/90	Jungblut et al.	514	171	

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Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	52.	5,006,345	4/9/91	Lang	424	467	
	53.	5,010,070	4/23/91	Boissonneault	514	171	
	54.	5,043,331	8/27/91	Hirvonen et al.	514	170	
	55.	5,089,482	2/18/92	Hermens et al.	514	58	
	56.	5,098,714	3/24/92	Wright et al.	424	473	
	57.	5,108,995	4/28/92	Casper	514	170	
	58.	5,130,137	7/14/92	Crowley, Jr.	424	422	
	59.	5,183,814	2/2/93	Dukes	514	171	
	60.	5,200,197	4/6/93	Wright et al.	424	473	
	61.	5,208,225	5/4/93	Boissonneault et al.	514	178	
	62.	5,210,081	5/11/93	Raveendranath et al.	514	179	
	63.	5,262,408	11/16/93	Bergink	514	182	
	64.	5,276,022	1/4/94	Casper	514	170	
	65.	5,280,023	1/18/94	Ehrlich et al.	514	177	
	66.	5,288,717	2/22/94	Raveendranath et al.	514	179	
	67.	5,362,720	11/8/94	Labrie	514	169	
	68.	5,382,573	1/17/95	Casper	514	170	
	69.	5,418,228	5/23/95	Bennink	514	182	
	70.	5,434,146	7/18/95	Labrie et al.	514	169	
	71.	5,464,871	11/1995	Kun et al.	514	617	
	72.	5,510,342	4/23/96	Washburn et al.	514	179	
	73.	5,541,172	7/30/96	Labrie	514	169	
	74.	5,545,634	8/13/96	Labrie	514	169	
	75.	5,547,948	8/20/96	Barcomb	514	170	
	76.	5,567,695	10/22/96	Labrie	514	169	
	77.	5,629,303	5/13/97	Labrie et al.	514	169	

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	78.	5,654,011	8/5/97	Jackson et al.	424	635	
	79.	5,753,639	5/19/98	Labrie	514	169	
	80.	5,759,576	6/2/98	Barcomb	424	479	
	81.	5,759,577	6/2/98	Barcomb	424	479	
	82.	5,807,586	9/15/98	Jackson et al.	424	630	
	83.	5,846,960	12/8/98	Labrie	514	169	
	84.	5,861,387	1/19/99	Labrie et al.	514	169	
	85.	5,861,431	1/19/99	Hildebrand et al.	514	557	
	86.	5,908,638	6/1/99	Huber et al.	424	465	
	87.	5,998,639	12/7/99	Raijmakers et al.	552	625	
	88.	Re. 36,247	7/6/99	Plunkett et al.	514	170	
	89.	6,040,333	3/21/00	Jackson	514	456	
	90.	6,221,379	4/24/01	Place	424	435	
FOREIGN PATENT DOCUMENTS							
		Document Number	Date	Country	Class	Subclass	Translation Yes   No
	91.	IL25265	12/31/69	Israel			X (Abstract only)
	92.	1214712	12/2/70	Great Britain			
	93.	DT2431694 A1	3/4/76	Germany			X
	94.	DT2624025 A1	12/9/76	Germany			X
	95.	1561244	2/13/80	Great Britain			
	96.	GB2096462A	10/20/82	Great Britain			
	97.	DE3341638 A1	11/17/83	Germany			X (Abstract)

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## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	98.	Andreolini, et al., <i>Estrogen Conjugates in Late-Pregnancy Fluids: Extraction and Group Separation by a Graphitized Carbon Black Cartridge and Quantification by High-Performance Liquid Chromatography</i> , Anal. Chem. <b>59</b> :1720-1725 (1987).
	99.	Desilva et al.; "Pyrene Sulphonyl Chloride as a Reagent for Quantitation of Oestrogens in Human Serum Using HPLC with Conventional and Laser-Induced Fluorescence Detection" <i>Biomedical Chromatography</i> <b>10</b> 318-324 (1996).
	100.	Erlit et al.; "Effect of megestrol acetate on flushing and bone metabolism in post-menopausal women" <i>Maturitas</i> <b>3</b> 167-172 (1981).
	101.	Fujino, et al., <i>3-(Difluoro-1,3,5-trianinyl)-1-(ethylthio)-2-n-propylbenz[f]isoindole as a Fluorescence Derivation Reagent for Estrogens in High-Performance Liquid Chromatography</i> , Chem. Pharm. Bull., <b>37</b> (7): 1939-1940 (1989).
	102.	Harnik; "Estrogenic estrane derivatives" 1189-1190 (1969).
	103.	Ishida, et al., <i>Determination of Oestrogens in Pregnancy Urine by High-Performance Liquid Chromatography with Fluorescence Detection</i> , Journal of Chromatography, <b>431</b> : 249-257 (1988).
	104.	Loprinzi et al.; "Megestrol Acetate for the Prevention of Hot Flashes" <i>The New England Journal of Medicine</i> <b>331</b> 347-352 (1994).
	105.	Novakovic, et al., <i>High-Performance Liquid Chromatographic Determination of Equine Estrogens with Ultraviolet Absorbance and Electrochemical Detection</i> , Journal of Chromatography A, <b>678</b> : 359-363 (1994).
	106.	Sakac, Marijan N. et al., "Chemical Behavior of 3, 17.beta.-dipropionoxy-9.alpha.-hydroxyestr-1,3,5(10)-trien-6-one," <i>DATABASE CHEMABS 'ONLINE'</i> , Database accession no. 128:180573 XP002171996, J. Serb. Chem. Soc., <b>63</b> (1): 21-24 (1998).
	107.	Sakac, Marija N. et al., "Synthesis of New Steroidal N-butyl-N-methyl-undecanamide Derivatives," <i>DATABASE CHEMABS 'Online'</i> , Database accession no. 133:335378 XP002171995, ZB. MATICE SRP. PRIR. NAUKE 96: 5-9 (1999)
	108.	Takadate, et al., <i>A Convenient Derivatization with Anion Exchange Resin Catalysts for High-Performance Liquid Chromatographic Analysis. I. Derivatization of Estrogens with Dansyl Chloride</i> , Chem. Pharm. Bull., <b>33</b> (11): 5092-5095 (1985).
	109.	Townsend, et al., <i>High-Performance Liquid Chromatographic Determination of Conjugated Estrogens in Tablets</i> , Journal of Chromatography, <b>450</b> : 414-419 (1988).
	110.	Wiese, Thomas et al., "Induction of the Estrogen Specific Mitogenic Response of MCF-7 Cells by Selected Analogues of Estradiol-17 $\beta$ : A 3D Study," <i>Journal of Medicinal Chemistry</i> , <b>40</b> (22): 3659-3669 (1997).
	111.	Yang et al., "The Hydroxylation and Amidation of Equilenin Acetate Catalyzed by Chloro[5,10,15,20-tetrakis(pentafluorophenyl)porphyrinato]manganese(III)," <i>Chem. Commun.</i> , <b>7</b> : 531-532 (2000).
	112.	Yang, Jerry et al., "Regioselective Oxidations of Equilenin Derivatives Catalyzed by a Rhodium(III) Porphyrin Complex-Contrast with the Manganese(III) Porphyrin," <i>Tetrahedron Letters</i> , <b>41</b> (42): 8063-8067 (2000).

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	113.	<i>Conjugated Estrogens</i> , The United States Pharmacopeia (USP), published by United States Pharmacopeial Convention, Inc., pp. 627-629 (2000).	
	114.	Synthetic Generic Conjugated Estrogens: Timeline, May 5, 1997, <a href="http://www.fda.gov/cder/news/cetimeline.htm">&lt;http://www.fda.gov/cder/news/cetimeline.htm&gt;</a> .	
	115.	FDA Statement on Generic Premarin, HHS News Press Release, P97-12, May 5, 1997, <a href="http://www.fda.gov/bbs/topics/NEWS/NEW00565.html">&lt;http://www.fda.gov/bbs/topics/NEWS/NEW00565.html&gt;</a> .	
	116.	New Drug Approval for Cenestin, Synthetic Conjugated Estrogens, A: March 24, 1999, <i>Questions and Answers</i> , <a href="http://www.fda.gov/cder/news/cenestin/qa.htm">&lt;http://www.fda.gov/cder/news/cenestin/qa.htm&gt;</a> .	
	117.	NDA 20-992 Cenestin™ (synthetic conjugated estrogens, A) Tablets Physicians Package Insert, pp. 1 - 10 (1999).	
	118.	NDA 20-992 Cenestin™ (synthetic conjugated estrogens, A) Tablets Patient Package Insert, pp. 11 - 13 (1999).	
	119.	Physician's Desk Reference, 53: 3367-3379 (1999).	

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